(c) Copy 5 shall be retained by the importer on file as his record of authority for the importation.

[36 FR 7815, Apr. 24, 1971, as amended at 36 FR 13387, July 21, 1971; 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and further amended at 45 FR 74715, Nov. 12, 1980; 51 FR 5319, Feb. 13, 1986; 53 FR 48244, Nov. 30, 1988; 62 FR 13969, Mar. 24, 1997; 75 FR 10682, Mar. 9, 2010]

EXPORTATION OF CONTROLLED SUBSTANCES

§ 1312.21 Requirement of authorization to export.

(a) No person shall in any manner export or cause to be exported from the United States any controlled substance listed in Schedule I or II, or any narcotic substance listed in Schedule III or IV, or any non-narcotic substance in Schedule III which the Administrator has specifically designated by regulation in § 1312.30 of this part or any non-narcotic substance in Schedule IV or V which is also listed in Schedule I or II of the Convention on Psychotropic Substances unless and until such person is properly registered under the Act (or exempted from registration) and the Administrator has issued a permit pursuant to § 1312.23 of this part.

(b) No person shall in any manner export or cause to be exported from the United States any non-narcotic controlled substance listed in Schedule III, IV, or V, excluding those described in paragraph (a) of this section, or any narcotic controlled substance listed in Schedule V, unless and until such person is properly registered under the Act (or exempted from registration) and has furnished a special controlled substance export invoice as provided by section 1003 of the Act (21 U.S.C. 953(e)) to the Administrator pursuant to § 1312.28 of this part.

(c) A separate authorization request is obtained for each consignment of such controlled substances to be exported.

[36 FR 7815, Apr. 24, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 52 FR 17290, May 7, 1987; 77 FR 4237, Jan. 27, 2012]

§ 1312.22 Application for export permit.

(a) An application for a permit to export controlled substances shall be made on DEA Form 161, and an application for a permit to reexport controlled substances shall be made on DEA Form 161R. Forms may be obtained from, and shall be filed with, the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Each application shall show the exporter's name, address, and registration number; a detailed description of each controlled substance desired to be exported including the drug name, dosage form, National Drug Code (NDC) number (in accordance with Food and Drug Administration regulations), the Administration Controlled Substance Code Number as set forth in Part 1308 of this chapter, the number and size of packages or containers, the name and quantity of the controlled substance contained in any finished dosage units, and the quantity of any controlled substance (expressed in anhydrous acid, base, or alkaloid) given in kilograms or parts thereof. The application shall include the name, address, and business of the consignee, foreign port of entry, the port of exportation, the approximate date of exportation, the name of the exporting carrier or vessel (if known, or if unknown it should be stated whether shipment will be made by express, freight, or otherwise, exports of controlled substances by mail being prohibited), the date and number, if any, of the supporting foreign import license or permit accompanying the application, and the authority by whom such foreign license or permit was issued. The application shall also contain an affidavit that the packages are labeled in conformance with obligations of the United States under international treaties, conventions, or protocols in effect on May 1, 1971. The affidavit shall further state that to the best of affiant's knowledge and belief, the controlled substances therein are to be applied exclusively to medical or scientific uses within the country to which exported, will not be reexported therefrom and that there is an actual need for the controlled substance for

medical or scientific uses within such country, unless the application is submitted for reexport in accordance with paragraphs (c) and (d) of this section. In the case of exportation of crude cocaine, the affidavit may state that to the best of affiant's knowledge and belief, the controlled substances will be processed within the country to which exported, either for medical or scientific use within that country or for reexportation in accordance with the laws of that country to another for medical or scientific use within that country. The application shall be signed and dated by the exporter and shall contain the address from which the substances will be shipped for exportation.

(b) There shall also be submitted with the application any import license or permit (and a translation thereof if in a foreign language) or a certified copy of any such license or permit issued by competent authorities in the country of destination, or other documentary evidence deemed adequate by the Administrator, showing that the merchandise is consigned to an authorized permittee, that it is to be applied exclusively to medical or scientific use within the country of destination, that it will not be reexported from such country, and that there is an actual need for the controlled substance for medical or scientific use within such country. (In the case of exportation of bulk coca leaf alkaloid, the submitted evidence need only show the material outlined in paragraph (a) of this section for such exportations.)

(c) Notwithstanding paragraphs (a) and (b) of this section, the Administration may authorize any controlled substance listed in Schedule I or II, or any narcotic drug listed in Schedule III or IV, to be exported from the United States to a country for subsequent export from that country to another country, if each of the following conditions is met, in accordance with §1003(f) of the Act (21 U.S.C. 953(f)):

(1) Both the country to which the controlled substance is exported from the United States (referred to in this section as the ''first country'') and the country to which the controlled substance is exported from the first country (referred to in this section as the ''second country'') are parties to the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971;

(2) The first country and the second country have each instituted and maintain, in conformity with such Conventions, a system of controls of imports of controlled substances which the Administration deems adequate;

(3) With respect to the first country, the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance has been issued by the country;

(4) With respect to the second country, substantial evidence is furnished to the Administration by the applicant for the export permit that—

(i) The controlled substance is to be consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance is to be issued by the country; and

(ii) The controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country;

(5) The controlled substance will not be exported from the second country;

(6) The person who exported the controlled substance from the United States has complied with paragraph (d) of this section and a permit to export the controlled substance from the United States has been issued by the Administration; and

(7) Within 30 days after the controlled substance is exported from the first country to the second country, the person who exported the controlled substance from the United States must deliver to the Administration documentation certifying that such export from the first country has occurred. If the permit issued by the Administration authorized the reexport of a controlled substance from the first country to more than one second country, notification of each individual reexport shall be provided. This documentation shall be submitted on company letterhead, signed by a responsible company official, and shall include all of the following information:

(i) Name of second country;

(ii) Actual quantity shipped;

(iii) Actual date shipped; and

(iv) DEA export permit number for the original export.

(d) Where a person is seeking to export a controlled substance for reexport in accordance with paragraph (c) of this section, the following requirements shall apply in addition to (and not in lieu of) the requirements of paragraphs (a) and (b) of this section:

(1) Bulk substances will not be reexported in the same form as exported from the United States, *i.e.*, the material must undergo further manufacturing process. This further manufactured material may only be reexported to a second country.

(2) Finished dosage units, if reexported, must be in a commercial package, properly sealed and labeled for legitimate medical use in the second country.

(3) Any proposed reexportation must be made known to the Administration at the time the initial DEA Form 161R is submitted. In addition, the following information must also be provided where indicated on the form:

(i) Whether the drug or preparation will be reexported in bulk or finished dosage units;

(ii) The product name, dosage strength, commercial package size, and quantity;

(iii) The name of consignee, complete address, and expected shipment date, as well as the name and address of the ultimate consignee in the second country.

(4) The application (DEA Form 161R) must also contain an affidavit that the consignee in the second country is authorized under the laws and regulations of the second country to receive the controlled substances. The affidavit must also contain the following statement, in addition to the statements required under paragraph (a) of this section:

(i) That the packages are labeled in conformance with the obligations of the United States under the Single Convention on Narcotic Drugs, 1961, the Convention on Psychotropic Substances, 1971, and any amendments to such treaties;

(ii) That the controlled substances are to be applied exclusively to medical or scientific uses within the second country;

(iii) That the controlled substances will not be further reexported from the second country, and

(iv) That there is an actual need for the controlled substances for medical or scientific uses within the second country.

(5) If the applicant proposes that the shipment of controlled substances will be separated into parts after it arrives in the first country and then reexported to more than one second country, the applicant shall so indicate on the DEA Form 161R, providing all the information required in this section for each second country.

(6) Within 30 days after the controlled substance is exported from the United States, the person who exported the controlled substance shall deliver to the Administration documentation on the DEA Form 161R initially completed for the transaction certifying that such export occurred. This documentation shall be signed by a responsible company official and shall include all of the following information:

(i) Actual quantity shipped;

(ii) Actual date shipped; and

(iii) DEA export permit number.

(7) The controlled substance will be reexported from the first country to the second country (or second countries) no later than 180 days after the controlled substance was exported from the United States.

(8) Shipments that have been exported from the United States and are refused by the consignee in either the first or second country, or are otherwise unacceptable or undeliverable, may be returned to the registered exporter in the United States upon authorization of the Administration. In these circumstances, the exporter in the United States shall file a written request for the return of the controlled substances to the United States with a brief summary of the facts that warrant the return, along with a completed DEA Form 357, Application for Import Permit, with the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for

the current mailing address. The Administration will evaluate the request after considering all the facts as well as the exporter's registration status with the Administration. If the exporter provides sufficient documentation, the Administration will issue an import permit for the return of these drugs, and the exporter can then obtain an export permit from the country of original importation. The substance may be returned to the United States only after affirmative authorization is issued in writing by the Administration.

(e) In considering whether to grant an application for a permit under paragraphs (c) and (d) of this section, the Administration shall consider whether the applicant has previously obtained such a permit and, if so, whether the applicant complied fully with the requirements of this section with respect to that previous permit.

[36 FR 7815, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 52 FR 17290, May 7, 1987; 62 FR 13969, Mar. 24, 1997; 72 FR 72927, Dec. 26, 2007; 75 FR 10682, Mar. 9, 2010]

§ 1312.23 Issuance of export permit.

(a) The Administrator may authorize exportation of any controlled substance listed in Schedule I or II or any narcotic controlled substance listed in Schedule III or IV if he finds that such exportation is permitted by subsections 1003(a), (b), (c), (d), or (f) of the Act (21 U.S.C. 953(a), (b), (c), (d), or (f).

(b) The Administrator may require that such non-narcotic controlled substances in Schedule III as shall be designated by regulation in §1312.30 of this part be exported only pursuant to the issuance of an export permit. The Administrator may authorize the exportation of such substances if he finds that such exportation is permitted by section 1003(e) of the Act (21 U.S.C. 953(e)).

(c) If a non-narcotic substance listed in Schedule IV or V is also listed in Schedule I or II of the Convention on Psychotropic Substances, it shall be exported only pursuant to the issuance of an export permit. The Administrator may authorize the exportation of such substances if he finds that such exportation is permitted by section 1003(e) of the Act (21 U.S.C. 953(e)).

(d) The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

(e) Each export permit shall be issued in septuplet and serially numbered, with all seven copies bearing the same serial number and being designated ''original'' (Copy 1), ''duplicate'' (Copy 2), etc., respectively. Each export permit shall be predicated upon an import certificate or other documentary evidence. Export permits are not transferable.

(f) No export permit shall be issued for the exportation, or reexportation, of any controlled substance to any country when the Administration has information to show that the estimates or assessments submitted with respect to that country for the current period, under the Single Convention on Narcotic Drugs, 1961, or the Convention on Psychotropic Substances, 1971, have been, or, considering the quantity proposed to be imported, will be exceeded. If it shall appear through subsequent advice received from the International Narcotics Control Board of the United Nations that the estimates or assessments of the country of destination have been adjusted to permit further importation of the controlled substance, an export permit may then be issued if otherwise permissible.

[36 FR 23625, Dec. 11, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 52 FR 17290, May 7, 1987; 72 FR 72929, Dec. 26, 2007]

§ 1312.24 Distribution of copies of export permit.

Copies of the export permit shall be distributed and serve purposes as follows:

(a) The original, duplicate, and triplicate copies (Copy 1, Copy 2, and Copy